DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

SOLICITOR

APR 0 4 1989

U S PATENT &
TRADEMARK OFFICE

#30

Re: Sensor Model Kelvin 500
Unipolar Pulse Generator, Model K Endocardial Lead, Model 5000 Transceiver, and Model 50 Lead Tester (Sensor Model Kelvin 500)
Docket No. 88E-0269

Charles E. Van Horn, Esq.
Deputy Solicitor, Solicitor's Office
U.S. Patent and Trademark Office
Washington, DC 20231

Dear Mr. Van Horn:

This is in regard to the patent term extension application for U.S. Patent No. 4,543,954 filed by Purdue Research Foundation, under 35 U.S.C. 156. The patent claims the medical device named the Sensor Model Kelvin 500 approved under the premarket approval application PMA 870054.

In the August 26, 1988 issue of the Federal Register, the Food and Drug Administration published its determination of the product's regulatory review period, as required under 35 U.S.C. 156(d)(2)(A). The notice provided that on or before March 24, 1989, 180 days after the publication of the determination, any interested person could file a petition with FDA under 35 U.S.C. 156 (d)(2)(B)(i) for a determination of whether the patent term extension applicant acted with due diligence during the regulatory review period.

The 180-day period for filing a due diligence petition pursuant to the notice regarding the Sensor Model Kelvin 500 has expired, and FDA has received no such petition. FDA, therefore, considers the Sensor Model Kelvin 500's regulatory review period determination to be final.

Please let me know if we can provide further assistance.

Sincerely yours,

Ronald L. Wilson

Ronald L. Wilson
Director
Health Assessment Policy Staff
Office of Health Affairs

cc: Clifford W. Browning
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